

REMARKS

Upon entry of the above amendment, claims 1-14 will be pending in the present application. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. In particular, claims 1-14 have been amended to recite a "hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof". Specific basis for this amendment may be found at page 2, 3rd paragraph. Claim 10 has been further amended to delete the phrase "preventing or" and to also recite specific gastrointestinal diseases as suggested by the Examiner.

The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Rejection of Claim 10 under 35 U.S.C. § 112, 1st paragraph

The Official Action states that claim 10 is rejected under 35 U.S.C. §112, 1st paragraph.

As the basis of this rejection, the Official Action states:

Claim 10 is rejected...because the specification, while being enabling for treating peptic ulcer, does not reasonably provide enablement for treating or preventing gastrointestinal disease.

Applicants respectfully traverse this rejection. However, solely to advance the prosecution of this application, applicants

have amended claim 10 to overcome the rejection of record by deleting the phrase "preventing or".

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw this rejection of claim 10.

2. Rejection of Claim 10 under 35 U.S.C. § 112, 2nd paragraph

The Official Action states that claim 10 is rejected under 35 U.S.C. §112, 2nd paragraph.

As the basis of this rejection, the Official Action states:

In claim 10, the term ---gastrointestinal disease--- is indefinite since specific diseases are not defined.

In claim 10, the term ---preventing--- is indefinite since the degree of prevention ... is not defined and furthermore, how this vulnerability is assessed to qualify for preventative treatment? The applicants are suggested to delete this term.

Applicants respectfully traverse this rejection. However, solely to advance the prosecution of this application, applicants have amended claim 10 to overcome the rejection of record by deleting the phrase "preventing or" and also by reciting specific gastrointestinal diseases. Basis for the specific gastrointestinal diseases recited may be found at page 16, 2nd paragraph.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw this rejection of claim 10.

3. Double Patenting Rejection of Claims 1-14

The Official Action states that claims 1-14 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,160,119 (the '119 patent).

As the basis for this rejection, the Official Action states:

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds directed to specific species are encompassed by the broader values R1, R2, R4a, R5a, R5b in the compounds of the cited patent.

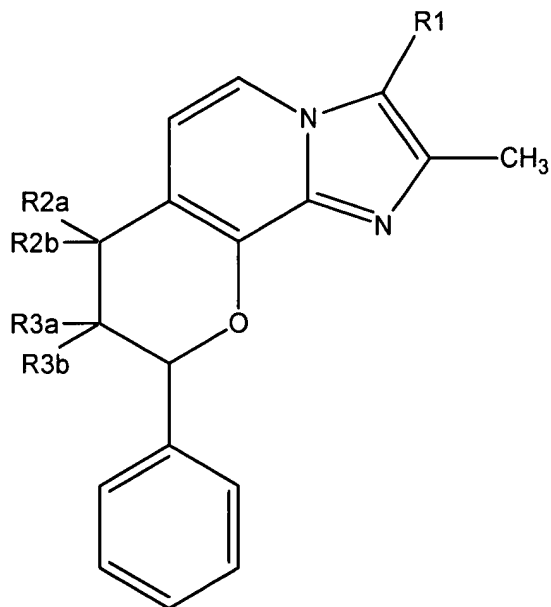
Applicants respectfully traverse the obviousness-type double patenting rejection over the '119 patent on the ground that the instant claims are patentable under the one-way obviousness determination. The one-way test is proper since the present application is the later filed application (See MPEP § 804).

Traversal: One-Way Obviousness Determination

Under a one-way obviousness determination, an obviousness-type double patenting rejection is improper where the application claims are patentably distinct from the prior patent claims.

A. The claimed subject matter

The present invention relates to a compound of formula 1



(1)

in which R₁ is methyl or hydroxymethyl,

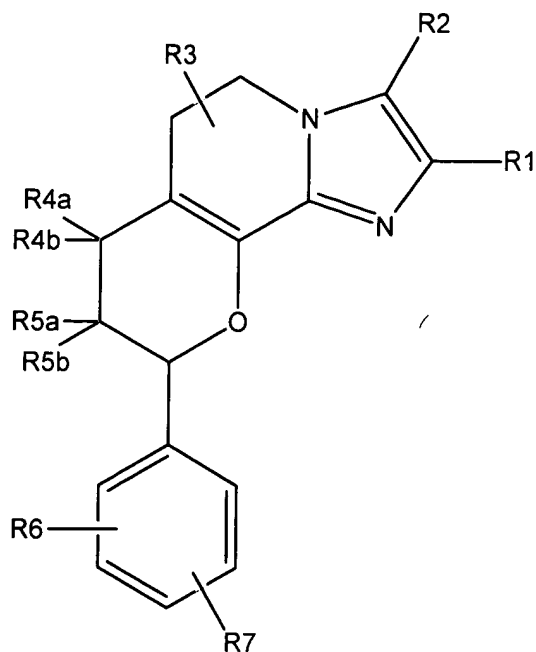
one of the substituents R_{2a} and R_{2b} is hydrogen and the other is hydroxy, methoxy, ethoxy, propoxy, isopropoxy, butoxy, methoxyethoxy or methoxypropoxy,

one of the substituents R_{3a} and R_{3b} is hydrogen and the other is hydroxy, methoxy, ethoxy, propoxy, isopropoxy, butoxy, methoxyethoxy or methoxypropoxy,

where R_{2a} or R_{2b} on the one hand and R_{3a} or R_{3b} on the other hand are not simultaneously hydroxy, or a hydrate, solvate, salt, hydrate of a salt or solvate of a salt thereof.

B. The claims of the '119 patent

In contrast, the '119 patent relates to a compound of formula



in which R1 is 1-4C-alkyl,

R2 is 1-4C-alkyl or hydroxy-1-4C-alkyl,

R3 is hydrogen or halogen,

one of the substituents R4a and R4b is hydrogen and the other is hydrogen, hydroxyl, 1-4C-alkoxy, 1-4C-alkoxy-1-4C-alkoxy or 1-4C-alkylcarbonyloxy, or in which R4a and R4b together are O (oxygen),

one of the substituents R5a and R5b is hydrogen and the other is hydrogen, hydroxyl, 1-4C-alkoxy, 1-4C-alkoxy-1-4C-alkoxy or 1-4C-alkylcarbonyloxy, or in which R5a and R5b together are O (oxygen),

where R4a, R4b, R5a and R5b are not simultaneously hydrogen,

or in which

one of the substituents R4a and R4b on the one hand and one of the substituents R5a and R5b on the other hand is in each case

hydrogen, and the other substituents in each case together form a methylenedioxy radical (-O-CH₂-O-) or an ethylenedioxy radical (-O-CH₂-CH₂-O-),

R6 is hydrogen, halogen, 1-4C-alkyl, 1-4C-alkoxy, 1-4C-alkoxycarbonylamino, 1-4C-alkoxy-1-4C-alkoxycarbonylamino or trifluoromethyl and

R7 is hydrogen, halogen, 1-4C-alkyl or 1-4C-alkoxy, or a salt thereof.

C. The differences between the claimed subject matter and the claims of the '119 patent

As conceded by the Examiner, the "conflicting claims are not identical". In particular, applicants note that the species compound of instant claim 8 contains a methoxyethoxy substituent in the same location that claim 7 of the '119 patent contains a hydroxy substituent.

D. Patentability of present claims demonstrated by Declaration under 37 C.F.R. §1.132

Applicants have submitted herewith a Declaration under 37 C.F.R. §1.132 which clearly demonstrates the patentability of the claimed compounds over those claimed in the '119 patent.

In particular, the Declaration demonstrates the results of tests carried out which compare the Example 8 compound of the '119 patent to each of the Examples 1-10 of the present application. These data compiled in Table 2 of the Declaration shows the unexpected result of the greater dose-related anti-secretory potency of the presently claimed compounds over those specifically exemplified in the '119 patent.

In particular, the data in Table 2 shows that, with the exception of "Compound J", both in the cis and trans series of experimental tests, the methoxy-ethoxy, ethoxy, methoxy-propoxy, isopropoxy and butoxy counterparts of the present application achieved 50% inhibition of gastric acid secretion (ED50) at considerably lower doses than their structurally closest related counterparts of the '119 patent. The three cited references cited in the Declaration that describe in greater detail the methodologies carried out in the experiments are attached herewith for the Examiner's convenience.

Accordingly, the presently claimed compounds are patentably distinct over the compounds claimed in claims 1-10 of the '119 patent.

Further, the Examiner is respectfully reminded that where a genus or generic formula disclosed (or claimed) in the art of record has a relatively large number of substituents that can be

made, such as the genus claimed by the '119 patent, a showing of obviousness is not readily accomplished. The fact that a claimed compound may be encompassed by a disclosed (or claimed) generic formula does not by itself render that compound obvious. See *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992). As such, since the '119 patent does not claim any species of the presently claimed invention, the presently claimed compounds can not be obvious in view of the genus claimed in the '119 patent.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-14 and allow these claims to proceed to grant.



CONCLUSION

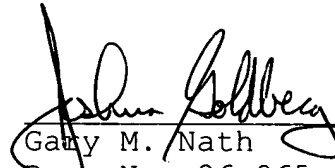
Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the rejections of pending claims 1-14. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,
NATH & ASSOCIATES PLLC

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